

## **REMARKS**

### *Status of Claims*

Claims 1 – 15, 18 – 32, 35 – 46, and new claims 47 – 49 are pending, with claims 1, 22, 38, 39, 43, and 48 being independent. Without conceding the propriety of the rejections, claims 1, 7, 12 - 14, 20, 22, 24, 29-31, 38-41, and 43-45 have been amended to even more clearly recite and distinctly claim the present invention and to pursue an early allowance. It is important to note that the amendments to these claims are merely formal and have not been made for reasons related to the statutory requirements for a patent; therefore, the scope of these claims has not been narrowed by the amendments.

New claims 47 – 49 have been added. Support for the amendments and new claims may be found in the original claims and throughout the specification, including, for example, at page 7, paragraph [0023]; pages 7 – 8, paragraph [0024]; page 9, paragraph [0029]; and page 10, paragraph [0030]. Therefore, no new matter has been added.

Claims 16, 17, 33, and 34 have been cancelled without prejudice to or disclaimer of the subject matter contained therein.

Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections in view of the foregoing amendments and the following remarks.

### *Rejection under 35 U.S.C. § 102*

Claims 1, 2, 6-10 14-27 and 31-46 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Howell, et al. (U.S. Patent No. 5,743,251). Applicants respectfully disagree with this rejection; therefore, this rejection is traversed.

Howell relates to an aerosol formed by supplying a material in liquid form to a tube and heating the tube such that the material volatilizes and expands out of an open end of the tube. (Abstract). Accordingly, Howell relates to aerosols generated without compressed gas propellants and methods and apparatus for generating these aerosols. Howell states that it is desirable for the aerosol to be approximately body temperature when inhaled and for mass median particle diameter of particles of the aerosol to be less than 2 microns, preferably between 0.2 to 2.0 microns, and more preferably between 0.5 and 1 micron. (Col. 9, lines 13-17). Howell further states that manipulation of parameters

of the aerosol generator such as the internal diameter of the tube, heat transfer characteristics of the of the tube, heating capacity of the heater, and the rate at which material in liquid form is supplied to the tube are expected to affect aerosol temperature and mass median particle diameter. (Col. 9, lines 27-32).

The examples of Howell reflect various runs performed with an apparatus for generating aerosols without compressed gas propellants. The examples demonstrate the operation of the apparatus using propylene glycol, glycerin, and mixtures thereof. The examples demonstrate the effects of various parameters on the mass median particle diameter of the ***total aerosol*** generated using the disclosed apparatus.

As recited in claim 1, a method for generating an aerosol is provided. The method comprises preparing a solution comprising a first component in a liquid component such that after volatilization, an aerosol is formed. The claim recites that the aerosol comprises at least first component aerosol particles and liquid component aerosol particles and the ***first component aerosol particles*** have a ***predetermined particle size distribution***. In the claimed method, the ***solution is prepared*** such that the ***amount of the first component*** therein is sufficient to achieve the predetermined particle size distribution of the first component aerosol particles.

To anticipate a claimed invention under §102, a reference must disclose each and every element of the claimed invention. See *Lindeman Maschinenfabrik GmbH v. American Hoist and Derrick Company*, 221 USPQ 481, 485 (Fed. Cir. 1984). Howell discloses examples that demonstrate the effects of various parameters on the mass median particle diameter of the ***total aerosol*** generated using the disclosed apparatus. It is respectfully submitted that in no way does Howell disclose or suggest forming an aerosol wherein the aerosol comprises at least first component aerosol particles and liquid component aerosol particles and wherein the ***first component aerosol particles*** have a ***predetermined particle size distribution***. It is further respectfully submitted that in no way does Howell disclose or suggest ***preparing a solution*** comprising a first component in a liquid component such that the ***amount of the first component*** therein is sufficient to achieve the predetermined particle size distribution of the first component aerosol particles.

As Howell does not disclose each and every element of the present claim 1, it cannot anticipate the subject matter of claim 1.

As recited in claim 22, a method for generating an aerosol is provided comprising preparing a solution comprising a first component in a liquid component such that after volatilization, an aerosol is formed. The claim recites that the aerosol comprises at least first component aerosol particles and liquid component aerosol particles and the *first component aerosol particles* have a *substantially monodispersed particle size distribution*. In the claimed method, the *solution is prepared* such that the *boiling point of the liquid component* is sufficient to achieve the substantially monodispersed particle size distribution of the first component aerosol particles.

As described above, Howell discloses the effects of various parameters on the mass median particle diameter of the *total aerosol* generated using the disclosed apparatus. It is respectfully submitted that in no way does Howell disclose or suggest forming an aerosol wherein the aerosol comprises at least first component aerosol particles and liquid component aerosol particles and wherein the *first component aerosol particles* have a *substantially monodispersed particle size distribution*. It is further respectfully submitted that in no way does Howell disclose or suggest *preparing a solution* comprising a first component in a liquid component such that the *boiling point of the liquid component* is sufficient to achieve the substantially monodispersed particle size distribution of the first component aerosol particles.

As Howell does not disclose each and every element of the present claim 22, it cannot anticipate the subject matter of claim 22.

As recited in claim 38, a method for generating an aerosol is provided comprising preparing a solution comprising a first component in a liquid component such that after volatilization, an aerosol is formed. The claim recites that the aerosol comprises at least first component aerosol particles and liquid component aerosol particles and the *first component aerosol particles* have a *predetermined and substantially monodispersed particle size distribution*. In the claimed method, the *solution is prepared* such that the *amount of first component* therein and the *boiling point of the liquid component* are

sufficient to achieve the predetermined and substantially monodispersed particle size distribution of the first component aerosol particles.

As described above, Howell discloses the effects of various parameters on the mass median particle diameter of the ***total aerosol*** generated using the disclosed apparatus. It is respectfully submitted that in no way does Howell disclose or suggest forming an aerosol wherein the aerosol comprises at least first component aerosol particles and liquid component aerosol particles and wherein the ***first component aerosol particles*** have a ***predetermined and substantially monodispersed particle size distribution***. It is further respectfully submitted that in no way does Howell disclose or suggest ***preparing a solution*** comprising a first component in a liquid component such that the ***amount of first component*** therein and the ***boiling point of the liquid component*** are sufficient to achieve the predetermined and substantially monodispersed particle size distribution of the first component aerosol particles.

As Howell does not disclose each and every element of the present claim 38, it cannot anticipate the subject matter of claim 38.

As recited in claim 39, a method for controlling particle size distribution of an aerosol is provided. The method comprises ***preparing a solution***, comprising a first component in a liquid component, such that the solution achieves a predetermined particle size distribution of first component aerosol particles.

As described above, Howell discloses the effects of various parameters on the mass median particle diameter of the ***total aerosol*** generated using the disclosed apparatus. It is respectfully submitted that in no way does Howell disclose or suggest ***preparing a solution***, comprising a first component in a liquid component, such that the solution achieves a ***predetermined particle size distribution*** of first component aerosol particles.

As Howell does not disclose each and every element of the present claim 39, it cannot anticipate the subject matter of claim 39.

As recited in claim 43, a method for providing a monodispersed particle size distribution of an aerosol is provided. The method comprises ***preparing a solution***,

comprising a first component in a liquid component, such that the solution achieves a monodispersed particle size distribution of first component aerosol particles.

As described above, Howell discloses the effects of various parameters on the mass median particle diameter of the **total aerosol** generated using the disclosed apparatus. It is respectfully submitted that in no way does Howell disclose or suggest **preparing a solution**, comprising a first component in a liquid component, such that the solution achieves a **monodispersed particle size distribution** of first component aerosol particles.

As Howell does not disclose each and every element of the present claim 43, it cannot anticipate the subject matter of claim 43.

For at least the above reasons, the rejection under 35 U.S.C. § 102(b) should be withdrawn. Such action is respectfully requested.

*Rejection under 35 U.S.C. § 103*

Claims 3-5, 11-13 and 28-30 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Howell in view of Rubsamen (U.S. Patent No. 5,819,726). Applicants respectfully disagree with this rejection; therefore, this rejection is traversed.

As described above, Howell relates to an aerosol formed by supplying a material in liquid form to a tube and heating the tube such that the material volatilizes and expands out of an open end of the tube. (Abstract). Also as described above, Howell discloses examples that demonstrate the effects of various parameters on the mass median particle diameter of the **total aerosol** generated using the disclosed apparatus.

Rubsamen relates to a method of treating patients suffering from a respiratory disease using a programmable, hand-held, self-contained drug dispensing device. (Abstract). Rubsamen discloses that an aerosol may be created by forcing drug through pores of a membrane, which pores have a size in the range of about 0.25 to 4.5 microns. (Col. 12, lines 1 – 3). Rubsamen further discloses that when the pores have this size, the particles, which escape through the pores, will have a diameter in the range of 0.5 to 9 microns. (Col. 12, lines 3 – 5). Rubsamen also discloses that creation of small particles may be facilitated by the use of a vibration device and that some adjustments can be made in the parameters such as the size of the pores, vibration frequency, pressure, and

other parameters based on the density and viscosity keeping in mind that the objective is to provide aerosolized particles having a diameter in the range of about 0.5 to 9 microns.

The Examiner cites Rubsamen as disclosing that it was known to treat respiratory ailments with budesonide and that particle size distribution can be controlled and adjusted to tailor the particular drug aerosol formulation to the particular ailment. (Col. 12, lines 1 – 58).

As described above, claim 1 recites a method for generating an aerosol comprising preparing a solution comprising a first component in a liquid component such that after volatilization, an aerosol is formed. The claim recites that the aerosol comprises at least first component aerosol particles and liquid component aerosol particles and the first component aerosol particles have a predetermined particle size distribution. In the claimed method, the solution is prepared such that the amount of the first component therein is sufficient to achieve the predetermined particle size distribution. Claims 3-5 and claims 11-13 are dependent upon claim 1 and thus recite further limitations.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2143.

It is respectfully submitted that even if there were some suggestion or motivation to combine the cited art and a reasonable expectation of success, the cited art when combined does not disclose or suggest all the claim limitations of claim 1 or claims dependent thereupon. Neither Howell nor Rubsamen discloses or suggests preparing a solution to be volatilized to form an aerosol wherein the solution comprising a first component in a liquid component is prepared such that the amount of the first component therein is sufficient to achieve the predetermined particle size distribution of the first component aerosol particles. Accordingly, it is respectfully submitted that even if Howell and Rubsamen are combined, the resulting combination does not produce all of the claim limitations.

As described above, claim 22 recites a method for generating an aerosol comprising preparing a solution comprising a first component in a liquid component such that after volatilization, an aerosol is formed. The claim recites that the aerosol comprises at least first component aerosol particles and liquid component aerosol particles and the first component aerosol particles of the aerosol have a substantially monodispersed particle size distribution. In the claimed method, the solution is prepared such that the boiling point of the liquid component is sufficient to achieve the substantially monodispersed particle size distribution. Claims 28 – 30 are dependent upon claim 22 and thus recite further limitations.

It is respectfully submitted that even if there were some suggestion or motivation to combine the cited art and a reasonable expectation of success, the cited art when combined does not disclose or suggest all the claim limitations of claim 22 or claims dependent thereupon. Neither Howell nor Rubsamen discloses or suggests preparing a solution to be volatilized to form an aerosol wherein the solution comprising a first component in a liquid component is prepared such that the boiling point of the liquid component is sufficient to achieve the substantially monodispersed particle size distribution of the first component aerosol particles. Accordingly, it is respectfully submitted that even if Howell and Rubsamen are combined, the resulting combination fails to produce all of the claim limitations.

For at least the above reasons, the rejection under 35 U.S.C. § 103 should be withdrawn. Such action is respectfully requested.

#### *Conclusion*

Without conceding the propriety of the rejections, the claims have been amended, as provided above, to even more clearly recite and distinctly claim Applicants' invention and to pursue an early allowance. It is important to note that the amendments to these claims are merely formal and have not been made for reasons related to the statutory requirements for a patent; therefore, the scope of these claims has not been narrowed by the amendments.

In view of the foregoing remarks, reconsideration of the claims and allowance of the subject application is earnestly solicited. The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Mel. M. Hayworth  
Melissa M. Hayworth  
Registration No. 45,774

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: August 11, 2003